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#13

DEC 28 1990

Tom M. Moran, Esq.
Syntex (U.S.A.) Inc.
3401 Hillview Avenue
P.O. Box 10850
Palo Alto, CA 94303

RE: Patent Term Extension
Application for
U.S. Patent No. 4,234,571
Issued: November 18, 1980

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,234,571 issued November 18, 1980, which claims the human drug product Synarel, is eligible for patent term extension under 35 USC 156. The period of extension has been determined to be two years.

The period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register of June 12, 1990. Under 35 USC 156(c):

$$\begin{aligned}\text{Period of Extension} &= 1/2 \text{ (Testing Phase)} + \text{Approval Phase} \\ &= 1/2 (455) + 2,725 \\ &= 1,818 \text{ days}\end{aligned}$$

Since the regulatory review period began June 2, 1981, after the original patent issue date, the entire period has been considered. No determination of a lack of due diligence was made.

The two year limitation of 35 USC 156(g)(6)(C) applies in the present situation because: (1) the patent was issued before the date of enactment (September 4, 1984) of 35 USC 156; (2) the date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving the approved product became effective (June 2, 1981) was before the date of enactment; and, (3) the date the new drug application was approved (February 13, 1990) was after the date of enactment. Since the period of extension calculated under 35 USC 156(c) for the patent cannot exceed two years under 35 USC 156(g)(6)(C), the period of extension will be for two years.

The 14 year exception of 35 USC 156(c)(3) does not operate to further reduce the period determined above.

A single request for reconsideration of this final determination as to eligibility and the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR 1.136(a) are not

applicable to this time period. In the absence of such request for reconsideration, the Commissioner will issue to the applicant for extension of the term of Patent No. 4,234,571 a certificate of extension, under seal, for a period of two years.

Upon issuance of the certificate of extension the following information will be published in the Official Gazette:

U.S. Patent No.:	4,234,571
Issued:	November 18, 1980
Applicant:	John J. Nestor et al.
Owner of Record:	Syntex (U.S.A.) Inc.
Title:	NONAPEPTIDE AND DECAPEPTIDE DERIVATIVES OF LUTEINIZING HORMONE RELEASING HORMONE
Classification:	514/15
Product Trade Name:	Synarel
Term Extended:	Two years

C.E. Van Horn

Charles E. Van Horn
Patent Policy and Programs Administrator
Office of the Assistant Commissioner for Patents

cc: Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fishers Lane, Room 11-44
Rockville, MD 20857

RE: Synarel
FDA Docket No. 90E-0156